



# Primary System Organ Class (SOC) Allocation in MedDRA®

## MSSO Videocast 01

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# Overview

- MedDRA as an ICH standard
- Reason for a primary SOC
- Rules for primary SOC allocation
- Changing a primary SOC allocation



# MedDRA as a Standard

- MedDRA developed by an ICH Expert Working Group
- Standardized, international, medically rigorous, maintained terminology
- Facilitates communication of adverse events in regulatory environment



## MedDRA as a Standard (cont)

- ICH-endorsed "*MedDRA Term Selection: Points to Consider*" document

"MedDRA is a standardized terminology. It is considered essential that *ad hoc* structural changes in MedDRA not occur. **The assignment of terms across SOCs is predetermined within the terminology and should not be altered by users.**"



# A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOCs
  - Allows grouping by different classifications
  - Allows retrieval and presentation via different data sets
- Example: PT *Dyspnoea* linked to:
  - SOC *Respiratory, thoracic and mediastinal disorders* (primary)
  - SOC *Cardiac disorders* (secondary)



# Reasons for a Primary SOC

- One SOC is primary; all others secondary
- Primary SOC used in cumulative data outputs (prevents “double counting”)
- Supports consistent data presentation for reporting to regulators



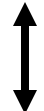
# Rules for Primary SOC Allocation

- General rule: prime manifestation site SOC
- Exceptions
  - SOC *Congenital, familial and genetic disorders*
  - SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
    - Exception: Cysts and polyps
  - SOC *Infections and infestations*

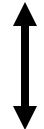


# Example of Multi-Axiality

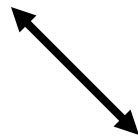
SOC = Respiratory, thoracic and mediastinal disorders



HLGT = Respiratory tract infections



HLT = Viral upper respiratory tract infections



PT = Swine influenza

SOC = Infections and infestations



HLGT = Viral infectious disorders



HLT = Influenza viral infections







# Changing a Primary SOC Allocation

- *Ad hoc* changes undermine MedDRA as a regulatory standard
- Users should submit proposal to change primary SOC assignment through Change Request process
  - MSSO considers justification and established allocation rules



# Example of Primary SOC Change

## **Previous version of MedDRA**

*SOC Blood and lymphatic system disorders*  
*PT Factor VIII deficiency*

## **Current version of MedDRA**

*SOC Congenital, familial and genetic disorders*  
*PT Factor VIII deficiency*



# Summary

- Reviewed concept of primary SOC allocation
- Discussed importance of adhering to allocation rules
- Feedback welcome!
  - Email MSSO Help desk
    - [mssohelp@ngc.com](mailto:mssohelp@ngc.com)